

§ 5.62

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuing of letters of filing in response to petitions for nutrient content claims and health claims:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Food Labeling, CFSAN.

(h) The following officials are authorized to issue letters concerning substances determined to be below the "threshold of regulation" under § 170.39 of this chapter:

(1) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director, Office of Policy, Planning and Strategic Initiatives, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

(4) The Directors of the Divisions of Petition Control and Product Policy, Office of Premarket Approval, CFSAN.

[49 FR 14936, Apr. 16, 1984, as amended at 49 FR 48183, Dec. 11, 1984; 52 FR 5951, Feb. 27, 1987; 58 FR 2410, Jan. 6, 1993; 59 FR 42492, Aug. 18, 1994; 60 FR 36594, July 17, 1995]

§ 5.62 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.

(a) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), the Director, Office of Field Programs, CFSAN, and the Director, Division of Enforcement, Office of Field Programs, CFSAN, are authorized to issue initial emergency permit orders under § 108.5 of this chapter.

(b) The following officials are authorized to issue notices of confirmation of effective date of final regulations on food matters promulgated under section 701(e) of the Federal Food, Drug, and Cosmetic Act:

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(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Food Labeling, CFSAN.

(4) The Director, Office of Special Nutritionals, CFSAN.

(5) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(6) The Director, Office of Seafood, CFSAN.

(7) The Director, Office of Field Programs, CFSAN.

(8) The Director, Office of Premarket Approval, CFSAN.

[59 FR 42492, Aug. 18, 1994]

§ 5.63 Detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors and District Directors are authorized to perform and to designate other officials to perform all of the functions of the Commissioner of Food and Drugs under:

(a) Section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(b) Section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(c) The Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

[48 FR 8442, Mar. 1, 1983, as amended at 54 FR 9034, Mar. 3, 1989; 60 FR 15871, Mar. 28, 1995]

§ 5.64 Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.

The Director and Deputy Director, Center for Food Safety and Applied Nutrition, are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter; which relate to setting standards for the National Laboratory Accreditation Program and approving

State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of these sections. The delegation excludes the authority to submit reports to the Congress.

[57 FR 43398, Sept. 21, 1992]

§ 5.66 Approval of schools providing food-processing instruction.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under § 113.10 of this chapter regarding the approval of schools giving instruction in retort operations, processing systems operations, aseptic processing and packaging system operations, and container closure inspections:

(a) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(b) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(c) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

[59 FR 42492, Aug. 18, 1994]

§ 5.67 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses or revocation of licenses and certain notices of revocation of licenses.

The Director and Deputy Director, Center for Biologics Evaluation and Research are authorized to issue:

(a) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for establishment or product licenses under § 601.4(b) of this chapter.

(b) Notices of opportunity for a hearing on proposals to revoke establishment or product licenses under § 601.5(b) of this chapter.

(c) Notices of revocation, at the manufacturer's request, of establishment or product licenses under §§ 601.5(a) and 601.8 of this chapter.

(d) Notices of revocation when the manufacturer has waived the opportunity for hearing under § 601.7(a) of this chapter.

[50 FR 30697, July 29, 1985, as amended at 54 FR 8318, Feb. 28, 1989; 56 FR 25025, June 3, 1991]

§ 5.68 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

The following officials are authorized to issue licenses under section 351 of the Public Health Service Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the act, and to revoke such licenses at the manufacturer's request:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8318, Feb. 28, 1989]

§ 5.69 Notification of release for distribution of biological products.

The following officials are authorized to issue written notices of release for distribution of licensed biological products under subchapter F (parts 600 through 699) of this chapter:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

(c) The Director and Deputy Director, Division of Product Quality Control, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989]

§ 5.70 Issuance of notice implementing the provisions of the Drug Amendments of 1962.

The Director, Deputy Center Director for Review Management, and Deputy Director, Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87-781) by announcing new or revised efficacy findings on human drugs that are or were subject to the